Evaluating Telehealth Homecare services - The TEN-HMS-Project: Medical, Quality of Life and Economic Efficiency Aspects

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Abstract
The aim of the TEN-HMS project is to prove that telehealth homecare can improve medical outcome for CHF patients as well as their quality of life and the efficiency of healthcare processes. Vital data (weight, pulse/rhythm, blood pressure) home monitoring equipment interfaces through cordless communications with the telephone. Data are transmitted through secure networks to a medical service centre. This world wide unique telemedical randomised controlled trial covers 200 home-monitored patients plus two control groups of 200 patients supported by a telephone service and 100 patients treated in a 'conventional' fashion in Germany, the Netherlands, and the United Kingdom. Leading cardiologists in 12 hospitals - who provide the telemonitoring service centres -, specialists and GPs are involved. All data are collected and analysed by an independent research institute. The study will furnish statistically reliable info: Primary outcome measure is bed-days occupancy in acute medical beds. Secondary outcomes include a composite measure of patient well-being, Best Medical Therapy Score, costs of care and mortality. High level political advisory boards accompany this study.

Telehealth homecare services: a definition
The primary object of the European Union TEN (Trans European Networks) project "European Home-Care Management System (TEN-HMS)" are *telehealth homecare services*. These are a subset of all generic health care services and can be defined as follows:

1. The *universe set* are *all generic health care services* (e.g. therapy by [heart] surgery; longer-term care at home; health information on nutrition).
2. Within this universe set, three specific *subsets* are of particular interest in our context:
   - Subset A: *services delivered to/in the home, i.e. outside medical establishments* (e.g. diagnostic or therapeutic home visits by a GP or nurse; emergency help on an air plane)
   - Subset B: *services delivered at a distance* (e.g. delivery of prescriptions by a courier, of radiology pictures or a second opinion by mail)
   - Subset C: *services delivered with the support of Information Society (IS) techniques* [as distinct from other medical techniques used, e.g., by a dentist or in an operating theatre] (applications of IS techniques are, e.g., electronic health records; obtaining a second opinion via videotelephone; capture with a digital camera and delivery of a dermatology image via fast data transfer)

The *intersection* of these three subsets provides us with the following definition of telehealth homecare services:

Telehealth homecare services are those health services which are delivered at a distance, to the home (or while travelling), and with the support of IS techniques

It is illustrated in *Figure 1*:

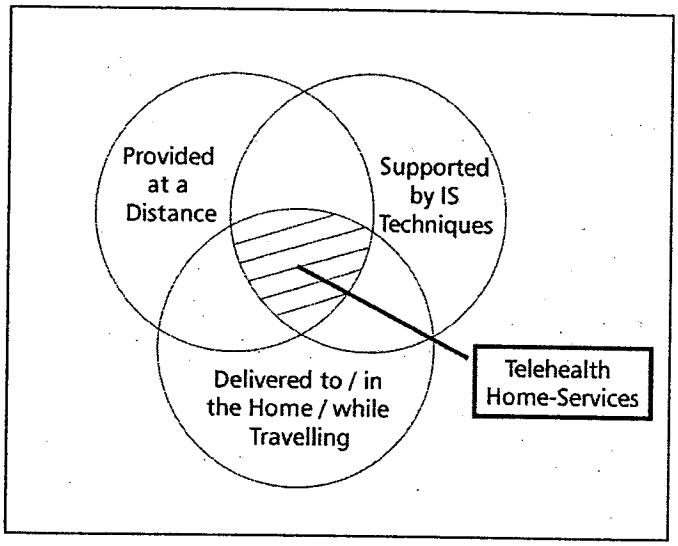

Figure 1: Subset of all telehealth home-services (Universe set: all health services)

Objectives of the study
The aim of the TEN-HMS project is to implement and evaluate a modular set of home telecare devices for chronically ill people, older/disabled citizens in need of long-term health care or patients who will benefit from constant vital data surveillance while at home. The concrete objectives are to thereby

- improve medical outcome for people suffering from chronic diseases and foster the uptake of 'best medical therapy'
- improve the quality of life of (chronically) ill people
- and to improve the efficiency (cost reduction) and continuity of healthcare processes.

In particular, the study will determine if *home monitoring* of patients with heart failure due to left ventricular systolic dysfunction at high-risk of hospital readmission can support these objectives, and if so whether home monitoring using devices to monitor weight, heart rate and rhythm, and blood pressure *and* telephone contact is superior to home monitoring by telephone contact alone.

The experimental design
For the study, 500 congestive heart failure (CHF) patients are being selected. 12 university and teaching hospitals in Germany, the Netherlands and the United Kingdom as well as local specialists and GPs are involved. By a random selection process, guided and controlled by an outside specialised institute, patients are allocated to three intervention groups:

Group 1: 100 patients, follow-up according to usual clinical practice
Group 2: 200 patients, follow-up according to usual clinical practice *supplemented* by monitoring using conventional telephone contacts

Group 3: 200 patients, follow-up according to usual clinical practice *supplemented* by monitoring using conventional telephone contacts *plus* twice daily telemonitoring of vital signs

The minimum duration of follow-up will be 15 months, the average duration around 18 months. For each individual patient, outcome measures will be adjusted accordingly.
This experimental design - size of intervention groups, length of duration and external methodological control - make for a world-wide unique telemedicine evaluation project.

Patient selection

To allow for comparable results across different countries and health systems and to secure methodological rigor, strict patient selection criteria have been established. Patients are included in the study only if they

- suffer from symptomatic heart failure (NYHA II-IV)
- require treatment with loop-diuretics (furosemide ≥40mg/day)
- have an ejection fraction <40% accompanied by left ventricular dilatation (adjusted for height – 30mm/m^2)
- are being prepared for discharge or having been discharged within the previous 2 weeks from hospital after an unplanned admission for worsening heart failure lasting >48 hours (patients must be identified within this 2-week interval and must be randomised within 4 weeks of discharge)
- having had one or more previous unplanned admissions for or with a cardiovascular problem lasting >48 hours within the last 24 months.

It must be patients who are over 18 years of age, who do not have a major cognitive defect, and who are willing and able to comply with home monitoring.

Evaluation/outcome measures and hypotheses

The impacts of the three types of intervention are measured and evaluated along the three dimensions of what we call the 'golden' evaluation triangle, depicted in *Figure 2*:

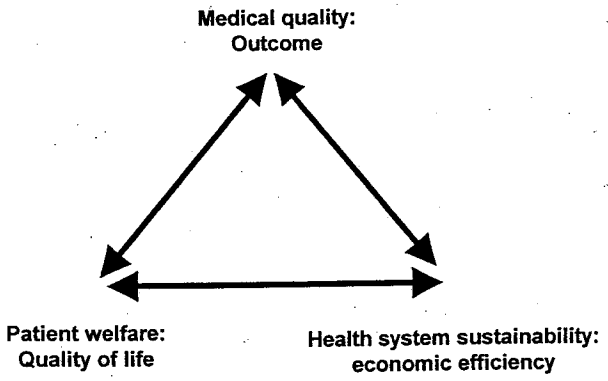

Figure 2: The "golden" evaluation triangle

For evaluation purposes, each of these dimensions is being assessed by means of several data:

a) Medical outcome

Medical outcome is measured at two levels:
The *primary* outcome measure is

- bed days (midnights in hospital) occupancy for all causes in acute medical / surgical beds.

This will be expressed as days-alive and out of hospital, adjusted for duration of follow-up/death.
Our hypothesis is that *control groups will spend 10 % of days-alive (about 41 days) in hospital, telemonitoring patients only 6 % (about 25 days)*

The expected statistical significance using a Wilcoxon rank-sum test is that 195 patients per arm will provide 90 % power to show significance at p=0.01. Assuming a drop from 10 % to 5 %, a sample size of only 129 would be required to obtain the same level of significance.
Secondary outcome measures are

- bed-days occupancy for cardiovascular reasons
- Best Medical Therapy Score (BMT: diuretics, ACE inhibitor, beta-blocker and low dose spironolactone) and
- mortality (all-cause and cardiovascular).

To these and other data, parametric statistical tests will be applied when the assumption of normally distributed data can be justified, otherwise non-parametric tests. It is known that particularly health economic data are generally highly skewed.

b) Patient quality of life

Changes in the patient quality of life is measured by

- a 5 point Likert scale (symptoms scores for breathlessness, fatigue, ankle swelling, and general well-being)
- New York Health Association (NYHA) classification
- the EuroQoL questionnaire
- the EuroHeart Failure Quality of Life score which has general and disease specific components.

These utility measures are administered at baseline, after four months, after 12 months and at the end of the study.

c) Economic efficiency/resource use

Considering continuous pressures to contain health system costs, a close monitoring and evaluation of resource use and organisational impact on a patient centred, seamless care system is mandatory. Here the following items will be monitored and measured:

- Medical resources:
  - hospital admissions and bed days
  - hospital and GP surgery consultations, home visits (time and transport)
  - prescription and drug costs
  - ambulance / parametric calls
- Patient / family resources:
  - costs of patient travel to GP / hospital
  - distance / time convenience factor
- Institutional resources:
  - Telemonitoring costs (and utility of equipment) for various scenarios of care delivery
  - organisational impact
  - usability and reliability of equipment / technology

Discussion

The health sector with expenditures in the amount of 6 - 11 % of GDP in Europe (1997, USA: 14 %) and up to 11 % of total employment is a key sector of all EU economies. For an ageing population, health services have a high priority. Here telemedicine is an exciting new technique for healthcare delivery. And a large number of studies have shown that telehealth techniques are acceptable to doctors and that patients are enthusiastic about it. A more patient-centred care, improved access for citizens in rural regions, better quality, greater efficiency and cost reductions are some of the high expectations. Compared to North America (and also, e.g., Australia), developments in Europe are lagging behind. With some exceptions in Scandinavia and the UK, pilot applications supported by research funds or based on local initiatives rather than being based on financial support by public health services or private insurers prevail. Direct delivery of telecommunications-based healthcare to the home is still mostly limited to some small-scale pilot projects, the same applies to monitoring of vital data of patients at home. However, also in Europe demand will increase rapidly:

the new health care paradigm of seamless, patient-centred care becomes more and more accepted, better informed citizens and patients will request modern, telecommunications-supported services.
Also, it can be expected that home care will expand considerably in the future, because it has - in most settings - various advantages when compared to (long-term) residential or hospital care:

- most citizens prefer to be cared for at home
- it usually relates to a higher quality of life
- sometimes life expectancy increases with home care
- costs of home healthcare are lower than those of hospital care.

However, in spite of all these high expectations and a lot of (cursory) empirical evidence, telemedicine in general and telehealth homecare in particular are not yet generally accepted techniques to be applied and reimbursed in national health system structures. A major barrier is that both telemedicine enthusiasts and industry have largely failed to provide methodologically reliable evidence from randomised controlled trials to prove these points. And proof of better medical outcome, benefits to patients and cost-effectiveness will more and more become mandatory, not only at the stage of market entry but also through the life cycle of a product or technology. It is here where the TEN-HMS project hopes to set a new standard. This also includes the involvement of advisory boards on which members of parliament, medical associations, ministries, public sickness and private insurance funds or patients are represented in order to involve the highest health policy making level at the earliest stage.

Perspectives

If the project will reliably proof the advantages of telehealth homecare, then we expect that in the longer run many sectors of society will benefit from this progress:

- Medicine: improved medical outcome
- Patients/families: improved quality of life for (chronically) ill and older people; patient-centred seamless care
- Health system resources: increased cost-efficiency
- Social / long-term care providers: new business models, personal attention focused on those clients in greatest need
- Industry: new markets, new jobs
- Society: improved ability and competence to better service the rapidly growing numbers of chronically ill and older people

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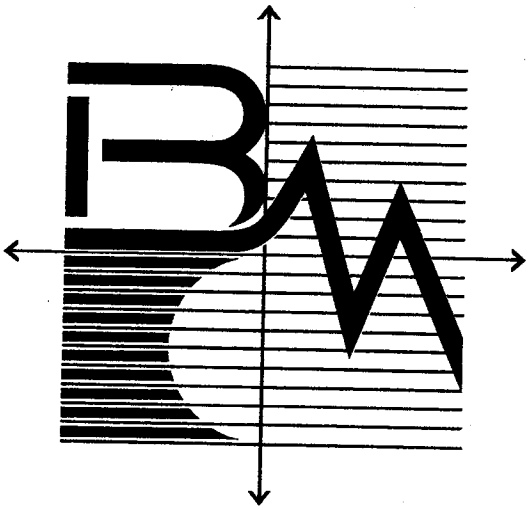

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12. Forumsgespräch am 17. November 2000

Telemedizin

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